Throughout the prosecution of this application, applicant has stressed the significant nature of his inventive contribution, which rests upon applicant's recognition, for the first time, that androgen alone, and without additional sterilizing agents, can be utilized for the purposes of contraception. Indeed, as has been emphasized throughout this case, as well as during the aforesaid personal interview, it was not previously known that these androgens alone could be used as a contraceptive. Furthermore, it certainly was not recognized that, to be contraceptively effective, these androgens would have to be used in at least certain dosage levels. It is for these basic reasons that applicant again submits that claims 1-15 and 17-21 are in condition for allowance. It is noted in this regard that the Examiner did not mention claims 17-21 in the official action dated January 19, 2001. However, since these claims were the subject of applicant's election of October 16, 2000, and since claims 17-21 actually depend from claims 1 and 2, it is apparent that this omission was unintentional, and it is therefore respectfully requested that the allowance of this application include these dependent claims.

Claims 1-15 have been rejected as being unpatentable under 35 U.S.C. § 112, second paragraph. The Examiner contends that the word "substantially" is vague. However, it is respectfully submitted that claim 1 in its present form clearly complies with all of the requirements of § 112, including the second paragraph thereof. It is clear that the subject matter of the present application requires recognition of the ability to use androgens such as those disclosed herein for contraceptive purposes. This clearly constitutes the subject matter of the present claims. However, in order to protect applicant from those who might add a small and ineffective amount of additional sterilent solely for the purposes of avoiding infringement of claim 1, and as has been done in numerous other issued patents,

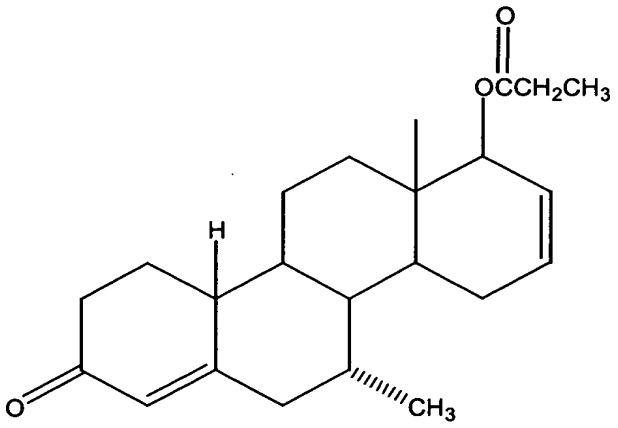
applicant has so defined his method. It is thus believed, as discussed during the aforesaid personal interview, that all of these claims, including claim 1, clearly meet all of the requirements for patentability.

Claims 1, 2 and 13-15 have been rejected as being unpatentable under 35 U.S.C. § 112, first paragraph. The Examiner contends that applicant demonstrates efficacy only for MENT. However, the present specification clearly and explicitly sets forth an entire range of androgens which can reach the goals of the present invention. While it is true that the specific data contained in this application is primarily directed to MENT, applicant's disclosure is not so limited, and, in fact, includes the entire range of these androgens, including a considerable number of the non-5-α-reducible androgens. Having recognized the efficacy of these androgens, applicant submits that it is entirely unnecessary to duplicate the data submitted for MENT for each of the other disclosed androgens. Based on this data, applicant has stated and acknowledged that this entire class of compounds would operate in substantially the same manner as MENT with similar androgenic activity. Indeed, based upon the present disclosure the Examiner is in no position to question applicant's assertions in this regard. That is, "the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure," and it is only after there has been some evidence that one of ordinary skill in the art would reasonably doubt the asserted utility that the burden shifts to applicant. *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). In this case, there is no such evidence, and indeed no basis for any assertion by the Examiner that the applicant's disclosure is anything but correct for the entire range of androgens disclosed and claimed therein.

It is therefore respectfully requested that this rejection be withdrawn since it can no longer be supported.

Claims 1, 2 and 13-15 have been rejected as being unpatentable over Tanabe *et al.* in view of Kumar *et al.* under 35 U.S.C. § 103(a). The Examiner contends that Tanabe *et al.* teach androgens useful in the control of male fertility, citing the abstract thereof. The Examiner further contends that Tanabe *et al.* states that they may be administered alone, citing column 15, lines 35-36, and that they have been shown to be useful in male contraceptives, citing column 17, lines 54-58. The Examiner concludes that it would have been obvious to use 7-methyl-16-ene nortestosterone as a male contraceptive in view of Tanabe *et al.* Regarding the claimed levels of LH and FSH as an indication of efficacy, this is said to be well known in the art, citing Kumar *et al.* FIG. 3. This rejection is respectfully traversed in view of the above arguments and for the further reasons set forth hereinafter.

Turning first to Tanabe *et al.*, this patent claims to disclose a particular class of steroids which are said to control male fertility in mammals. Applicant submits that the compounds disclosed in Tanabe *et al.* do not provide the results set forth in the present claims. In fact, by the very disclosure of Tanabe *et al.*, it can be seen that these compounds are incapable of providing the results required by the present claims. According to Tanabe *et al.*, the particular class of compounds to which that patent is directed, is as follows:



These compounds cannot possibly meet the requirements of claim 1 with respect to providing male subjects with blood levels of LH and FSH of 2.5 IU/L or less and of testosterone of 10 mmol/liter or less. Indeed, these compounds cannot meet the requirement for comprising a male contraceptive when used in accordance with the present method. One of ordinary skill in this art, as was discussed during the aforementioned personal interview, reviewing the disclosure of the Tanabe *et al.* patent, would immediately realize this. Turning, for example, to columns 27 and 28 of Tanabe *et al.*, the patentees themselves state that "[n]ormally potent androgens have a high RBA (receptor binding assay) value, and materials with low RBA's have low activity." In the results submitted by these patentees, the materials of that invention were compared to 17α-methyl testosterone, which was arbitrarily assigned a value of 1.0 for oral and subcutaneous androgenic activity. In discussing these figures, it was noted that the compounds of the invention have low values for receptor binding, and it was thus admitted that the usual predictor of activity suggests that the present compounds would be inactive, but that instead they were said to be extremely active. The data indicates, in fact, an RBA of 8% for the compounds of Tanabe *et al.*, as compared to 20% for testosterone. Since binding

capacity is, admittedly, an important element in androgenic activity, there is no explanation for this discrepancy. Indeed, the only suggestion in the entire Tanabe *et al.* patent that these compounds would have such activity is a notation that the androgenic activity subcutaneously was 40 in this case. However, there is no data whatsoever in Tanabe *et al.* to even suggest how this result was arrived at, and what it actually means. It is therefore clear that anyone of even less than ordinary skill in this art realizing that the compounds of Tanabe *et al.* have such low binding capacity, would not only realize that these were not active androgenic compounds, but would have no reason whatsoever to believe that these compounds could meet the requirements of the present invention and, by themselves, constitute male contraceptives. The fact of the matter is that claims 1 and 2 do not read on the compounds of Tanabe *et al.*, and this disclosure does not obviate the present invention.

Beyond all of the above, it is further noted that, even where Tanabe *et al.* discusses effective dosages of these compounds, there is a discussion, for an average 70 kg human, of from 70 to 700 mg/day. On the other hand, the present application, and referring in particular to claims such as claims 9-11, requires dosages of from 200 to about 2000 micrograms/day. Again, there is no suggestion whatsoever that these dosages, when applied to the compounds of the present invention, much less to those of Tanabe *et al.*, would result in the highly unexpected and improved results attainable in connection with the present invention.

In an attempt to overcome these obvious deficiencies of Tanabe *et al.*, the Examiner relies upon Kumar *et al.* The Kumar *et al.* reference, however, much like the previously submitted Sundaram *et al.* reference, includes a recognition of the fact that MENT (7α-methyl-19-nortestosterone) is a more active androgen than testosterone. It is clear, however, that there is

no suggestion whatsoever in Kumar *et al.* (as was the case with Sundaram *et al.*) that MENT could be used as a sterilizing agent for a male subject for the purposes of contraception. In this regard, the Examiner made reference to FIG. 3 in Kumar *et al.* As was discussed during the interview, however, the data in this Figure shows reduction in serum levels of LH and FSH for both MENT and testosterone, but clearly does not show anything with respect to the effect of MENT on serum levels of testosterone, and certainly not the required 10 mmol/liter or less of claim 1 herein. Without this knowledge, however, there would have been no incentive whatsoever to consider MENT or any other such androgens for use in the method of this invention.

With this understanding, it can now be seen quite clearly that the cited combination of references does not suggest the method of claims 1 or 2, or the use of any androgen for male contraception so as to provide low levels of LH and FSH of 2.5 IU/L or less and of testosterone of 10 mmol/liter or less, in which the androgen is substantially the only sterilizing agent administered to the male subject for purposes of contraception.

It is therefore respectfully submitted, as discussed during the aforesaid personal interview, that there is now full agreement that the present claims are clearly directed to patentable subject matter, and reconsideration and allowance of this application is therefore respectfully solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Finally, if there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

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